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SEP 24 2012

510(k) Summary

Avery Dennison Belgie, BVBA

BeneHold CHG Transparent Film Dressing

1. **Submitter Information**

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Date Prepared:	December 27, 2011

2. **Device Name**

Trade Name:	BeneHold CHG Transparent Film Dressing
Common Name:	Dressing, Wound, Drug
Classification Name:	Unclassified

3. **Predicate Device(s)**

- K063458, 3M Tegaderm CHG Dressing

4. **Device Description**

The BeneHold CHG Transparent Film Dressing is used to cover and protect catheter sites and to secure devices to the skin. The dressing consists of a transparent film with an acrylic adhesive which contains Chlorhexidine Gluconate (CHG), a well-known antiseptic agent with broad-spectrum antimicrobial and antifungal activity. The dressing is a barrier to liquid (waterproof), bacteria and yeast, and protects the IV site from outside contamination. The dressing absorbs between 8 and 21 ml of fluid depending on the dressing size. In vitro testing (barrier, kill time and log reduction) demonstrates that the BeneHold CHG Transparent Film Dressing has an antimicrobial effect against, and is a barrier to, the passage of a variety of gram-positive and gram-negative bacteria, yeast and fungus in the dressing. BeneHold CHG Transparent Film Dressing is transparent, allowing continual site observation, and is breathable, allowing good moisture vapor exchange.

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5. **Indications for Use**

The BeneHold CHG Transparent Film Dressing is intended to cover and protect catheter sites and to secure devices to the skin. Common applications include securing and covering IV catheters, other intravascular catheters and percutaneous devices.

6. **Technological Characteristics and Substantial Equivalence**

Both the BeneHold CHG Transparent Film Dressing and 3M Tegaderm CHG Dressing are wound dressings used to cover and protect catheter sites and secure devices to the skin via adhesion of the dressing to the skin.

7. **Performance Testing**

The BeneHold CHG Transparent Film Dressing was evaluated to assure conformance to design specifications. The following performance tests were performed:

- Fluid Handling Capacity
- Static Absorption
- Moisture Vapor Transmission Rate
- Peel Adhesion
- Liner Release
- Finat Tack
- Seal Strength
- Die Migration
- CHG/PCA Content
- Antimicrobial Effectiveness
- Bacterial/Viral Barrier
- Sterility

The BeneHold CHG Transparent Film Dressing was also evaluated for safety concerns relative to biocompatibility. The evaluations showed that there irritation is negligible, and that there is no evidence the device causes cell lysis or toxicity, nor is there evidence of delayed dermal contact sensitization.

8. **Conclusion**

Testing indicates that the BeneHold CHG Transparent Film Dressing is substantially equivalent in terms of both indications for use and technology to the predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Avery Dennison Belgie, BVBA
% Avery Dennison Corporation
Mr. Jerzy Wojcik
Manager, Regulatory Affairs
20 North Wacker Drive, Suite 2240
Chicago, Illinois 60606

SEP 24 2012

Re: K113836
Trade/Device Name: BeneHold CHG Transparent Film Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 14, 2012
Received: September 18, 2012

Dear Mr. Wojcik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113836

Indications for Use

510(k) Number (if known):

Device Name: BeneHold CHG Transparent Film Dressing

Indications for Use:

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Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113836